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COPY N° 3

Functional Specifications
TCM

Order: N9501

Customer: Connaught - Canada

Reference: NN9501F

Version: 1

Date: February 2, 1996

This document contains 30 pages, one page of Appendix B and an enclosure.

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TABLE OF CONTENTS

1. INTRODUCTION 3
1.1 REFERENCES 3
2. GENERAL DESCRIPTION 4
2.1 PROCESS DESCRIPTION 4
2.1.1 Process diagram (Sheets 1-4) 6
2.1.2 Mechanics layout 10
2.2 COMPUTER DESCRIPTION 10
2.2.1 Hardware architecture 10
2.2.2 Software architecture 11
2.4 TECHNICAL NOTES 16
2.4.1 Performances 16
2.4.2 Services required 16
2.4.3 Limits 17
2.4.4 Working environment 17
2.4.5 Expandability, interface, options 17
3. FUNCTIONS 18
3.1 ACQUISITION SYSTEM 18
3.1.2 PROCESSING SYSTEM 18
3.2 INSPECTIONS 20
3.2.1 Station TV1 Station TV2 20
3.3 MECHANICS 21
3.3.1 Loading 21
3.3.2 Transportation method 21
3.3.3 Output 22
3.3.4 Protections 22
3.4 SAFETY - ERROR AND ALARM MESSAGES 22
3.4.1 Safety 22
3.4.2 Error and alarm messages 23
4. INTERFACE 26
4.1 ACCESS LEVELS 26
4.1.1 Operator 27
4.1.2 Supervisor 29
4.1.3 Maintenance technician 29
5. GLOSSARY 30

APPENDIX B: Classes of Defects and Reject Priority

ENCLOSURES
Enclosure 1: LAY-CONNAUGHT-13 1 (sheet, rev. 2)

1. INTRODUCTION

This document is prepared by Brevetti C.E.A. S.p.A. in order to define functional criteria of TCM machine, as required by the Customer in the User Requirement Specification [1].

This document is prepared in accordance with what foreseen in I4.15 Instruction (Standard Format of Machine Documentation) [2].

This document is produced by the System Analysis Department and approved by Quality Assurance and then submitted to the Customer's approval, as foreseen by the Quality Plan [3].

1.1 REFERENCES

When there is a reference to another document only the number is reported into square brackets as indicated in the following table:

N.	RIF.	DOCUMENTO
[1]	N.A.	SPECIFICATIONS FOR BREVETTI AUTOMATIC INSPECTION MACHINE AND BREVETTI JUPITER LEAK DETECTOR - dated June 26, 1995
[2]	I4.15	Standard Format of Machine Documentation
[3]	NN9501Q	Quality Plan
[4]	NN9501U	TCM User Manual
[5]	NN9501V	TCM Maintenance Manual
[6]	NN9501Z	Software Configuration, SP Programs and Parameters

2. GENERAL DESCRIPTION

TCM machine is designed to be inserted in modern pharmaceutical product lines. It is installed downstream from filling and freeze-drying lines and before the line for particle inspection.
TCM machine is manually loaded with boxes or directly in line from the ampoule filling machine; the output of rejected containers occurs on standard stainless steel C.E.A. boxes, while the accepted containers are addressed to the downstream machine (ATM18) by means of two linear guides.

The TCM machine consists of:

a mechanic part charged with transporting the containers along the test path;

an electric and electronic part which handles the mechanic part management and its interface with the production line. Furthermore it permits the user's monitoring of the process;

external keyboard and monitor, used as user/machine interface.

2.1 PROCESS DESCRIPTION

Process control is totally automatic. Each container undergoes a series of inspections performed by telecameras. It is enough that only one of the tests results negative for the container to be rejected.
Containers are transported along the test path including the tests which are listed here below:

Station	Inspection	Ref. U.R.S. [1]
TV1	Tip (symmetry and burnings)	N.A.
TV2	Tip (symmetry and burnings)	N.A.

The specifications of the different inspection stations and of the image processing method are present in Chapter 3 (Functions) of this document.

The process diagram is shown in the next pages. Sheet 1 shows the process flow chart for all inspection stations: if inspection is enabled, the images are processed and the result is stored as an active "reject" or "accept" flag in the shift register.

The acquired scans are processed while the machine is carrying the container to the next station. If this container is ready for the image acquisition, but the processing of the previous images was not completed, the machine stops and the container is indicated as reject. This happens when the machine speed is too fast or the test program is too long.
The diagram shows from the functional point of view the main functions performed by the system during operation. A more detailed explanation of the routines the software executes to test the various sections of the machine is given in the Software Design Specification.

Fig. 2.1 shows the layout of the stations to which we refer in the process diagram.

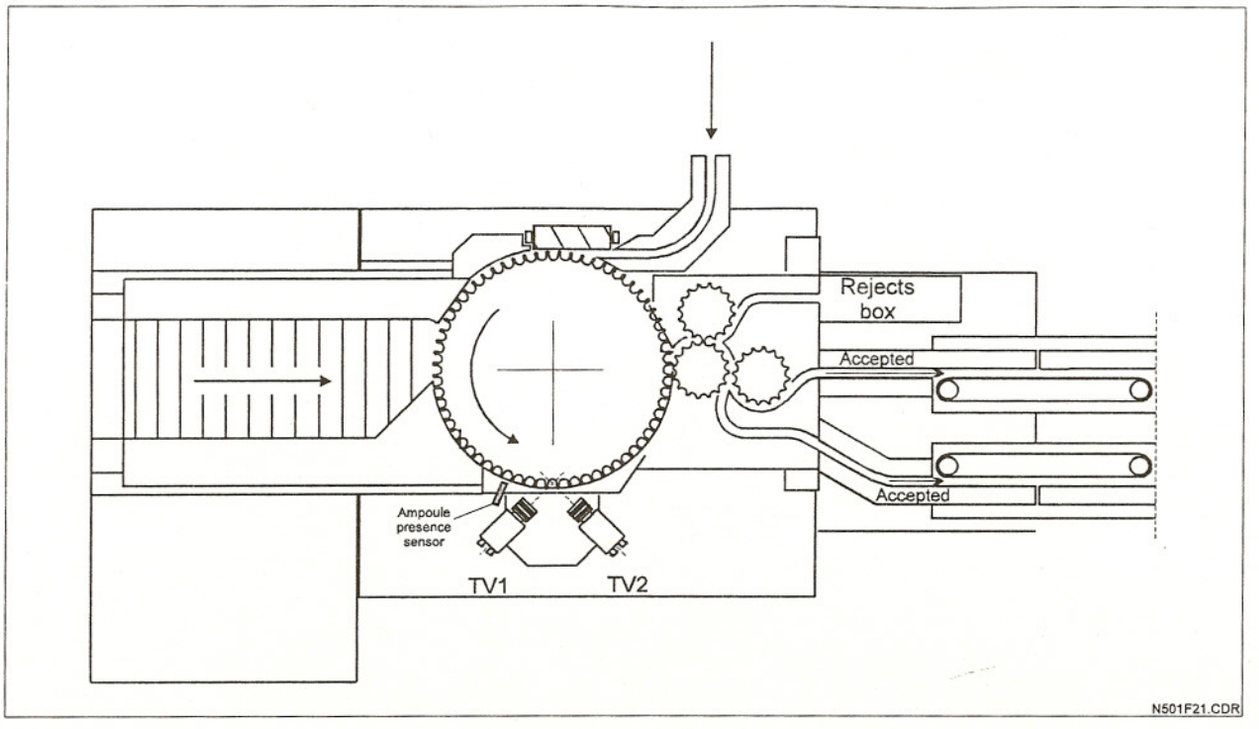
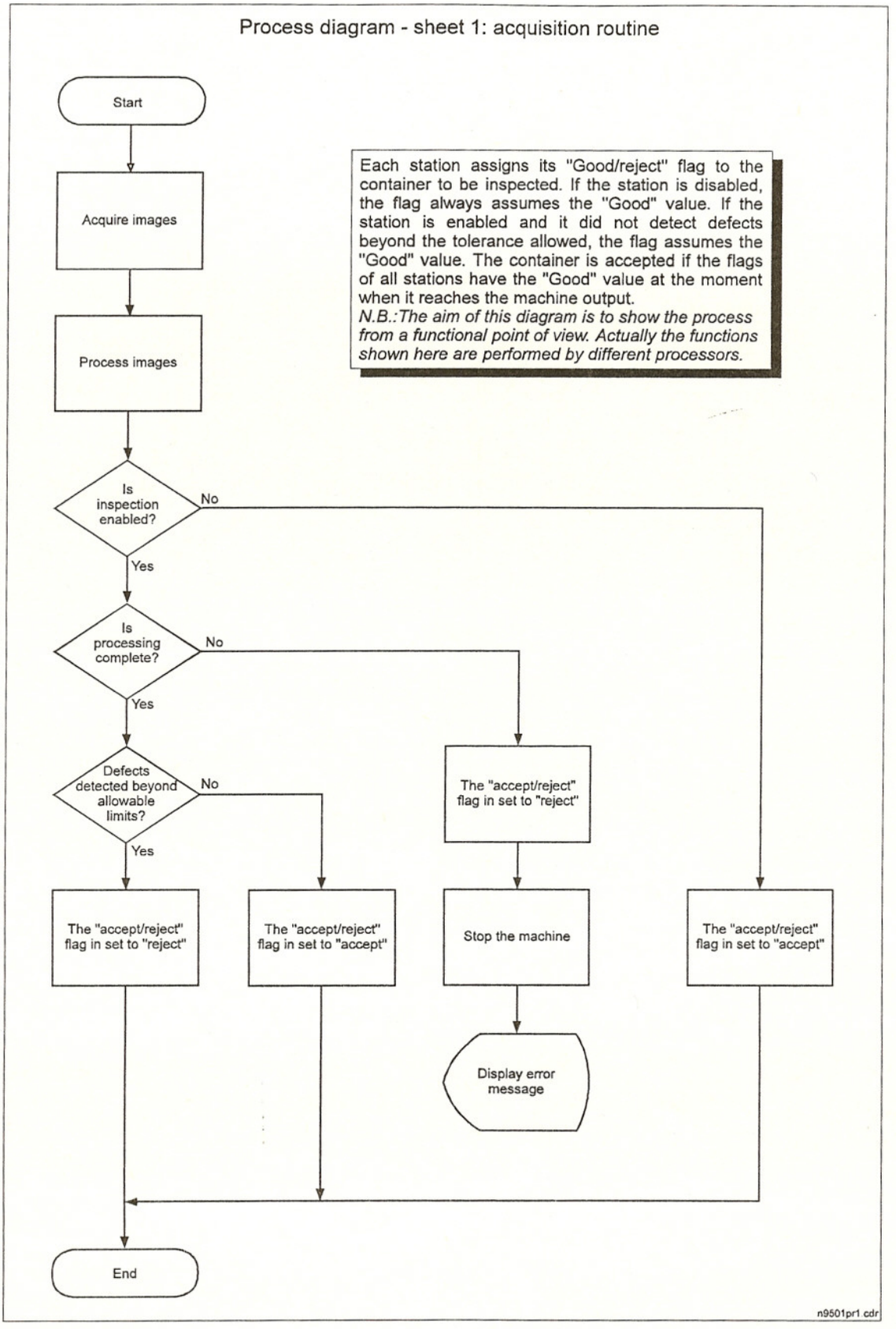
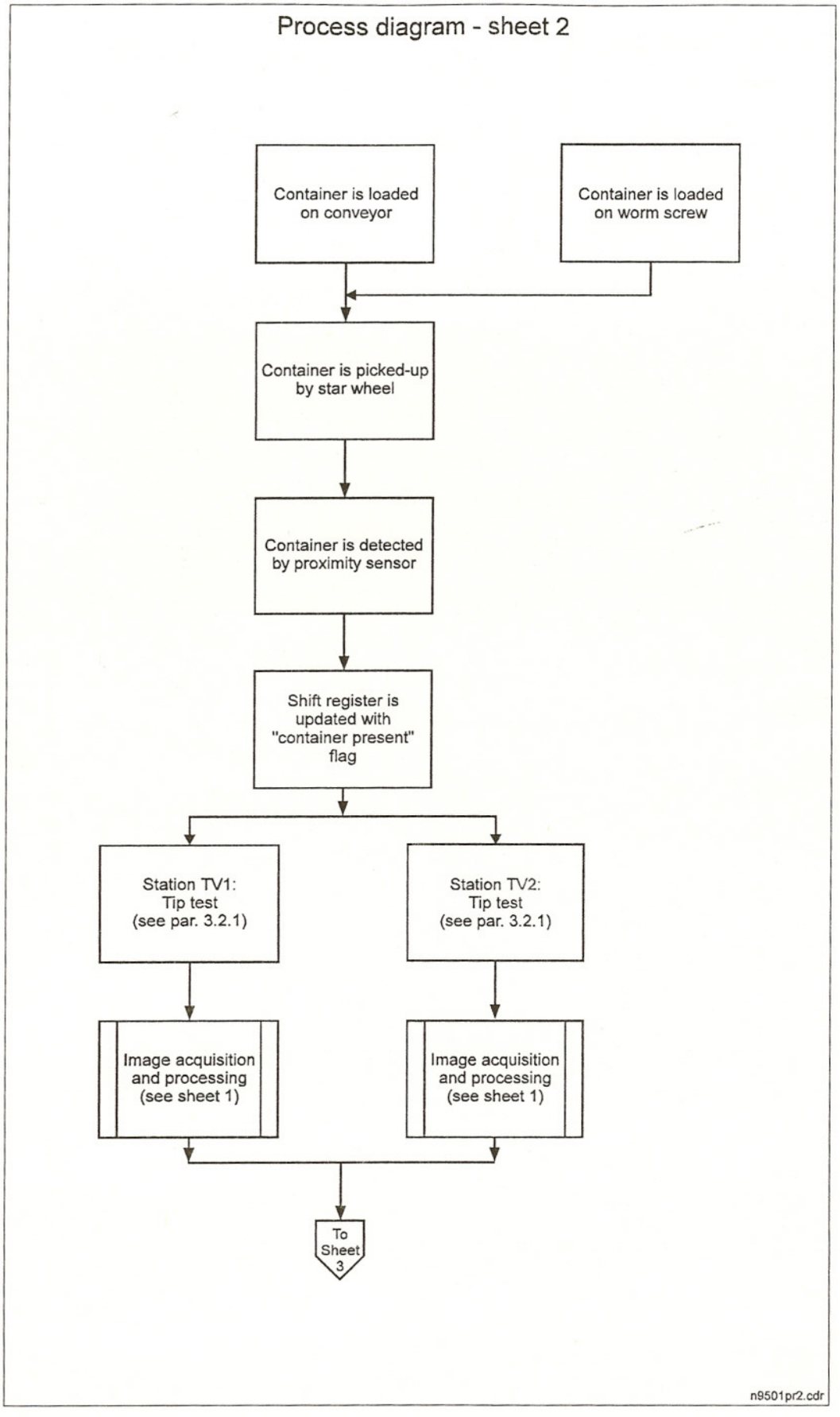
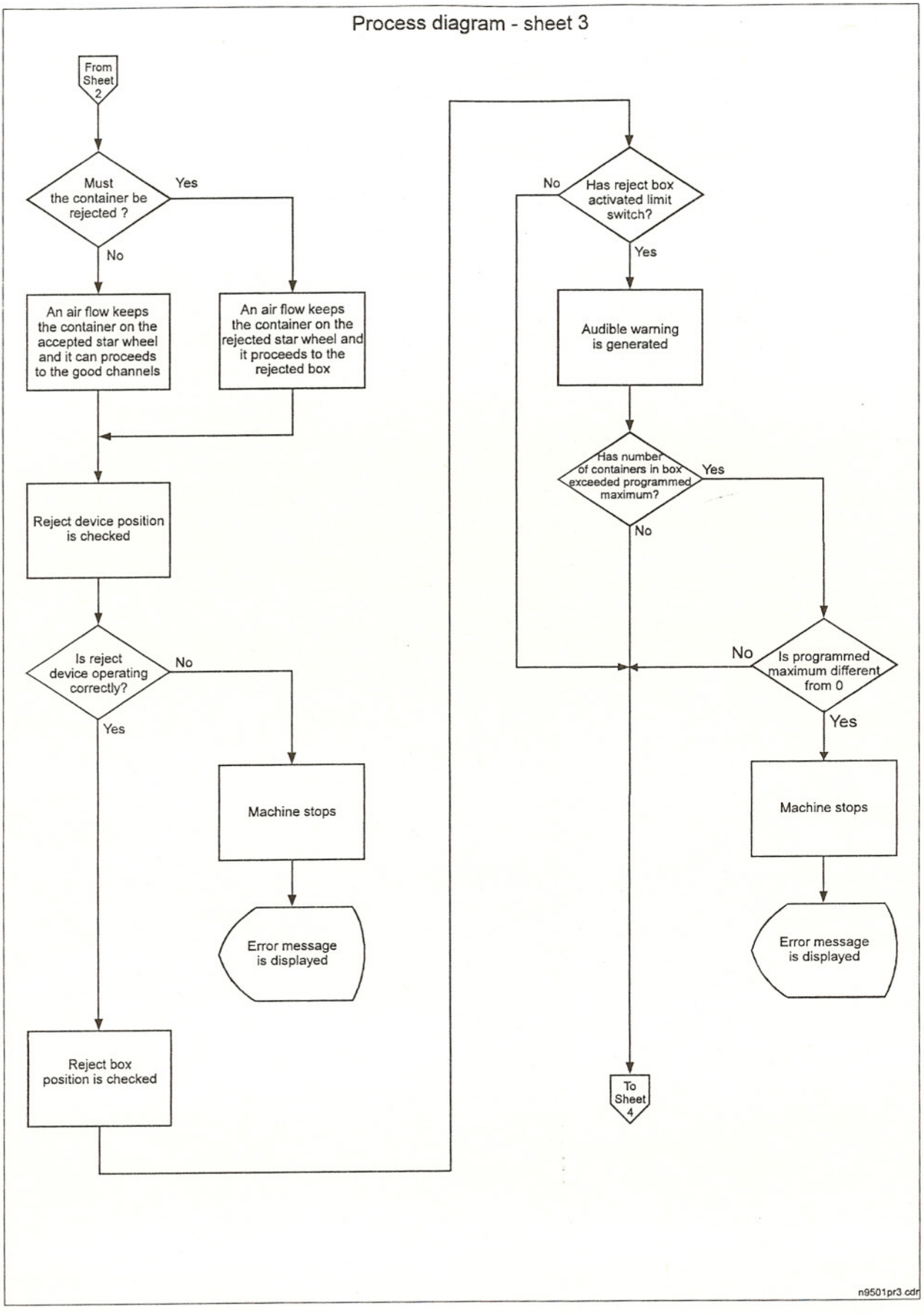


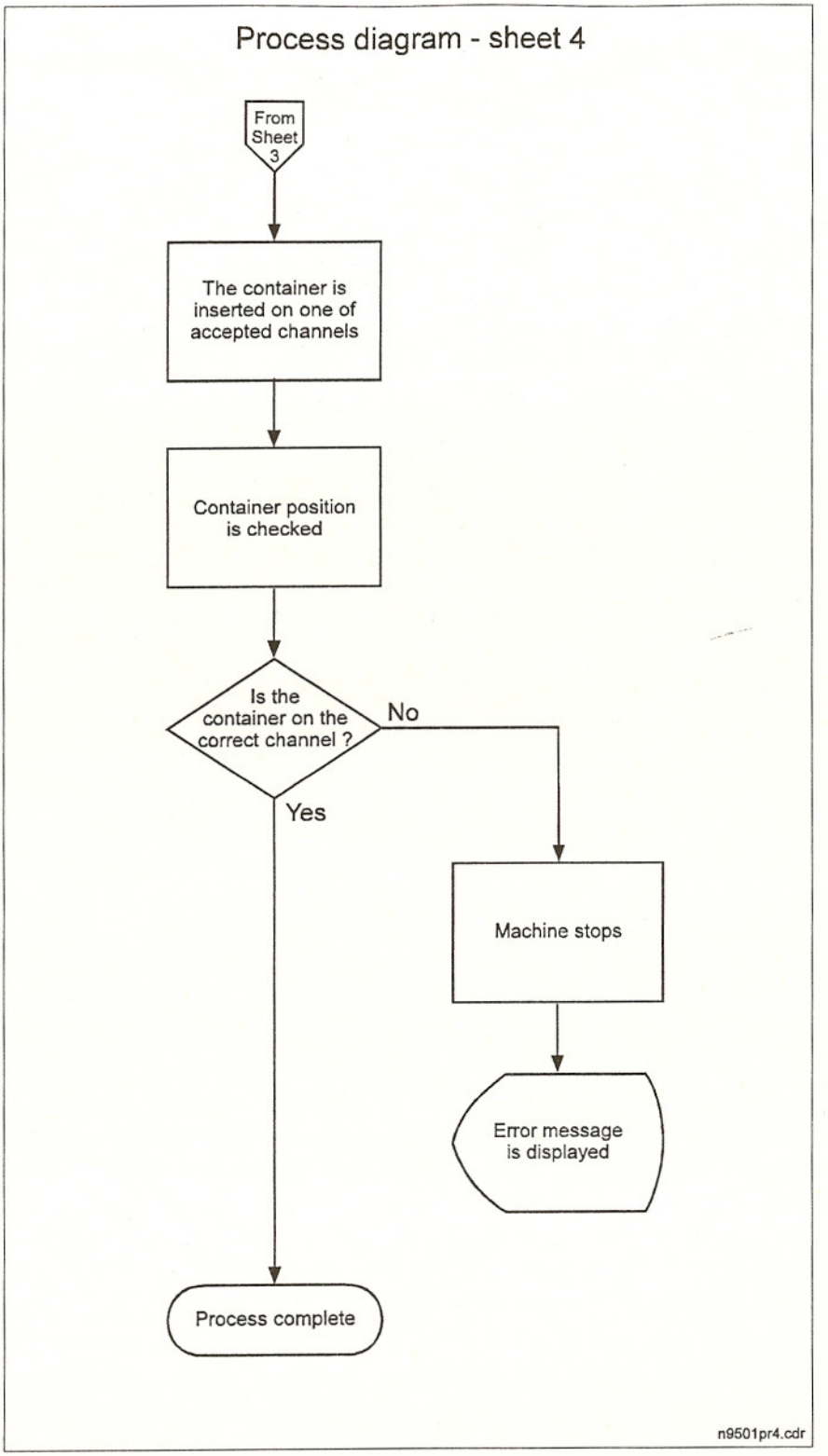
Fig. 2.1 - Inspection station layout

2.1.1 Process diagram (Sheets 1-4)


Process diagram - sheet 1: acquisition routine
Start
Acquire images
Process images
Each station assigns its "Good/reject" flag to the container to be inspected. If the station is disabled, the flag always assumes the "Good" value. If the station is enabled and it did not detect defects beyond the tolerance allowed, the flag assumes the "Good" value. The container is accepted if the flags of all stations have the "Good" value at the moment when it reaches the machine output.
N.B.:The aim of this diagram is to show the process from a functional point of view. Actually the functions shown here are performed by different processors.
Is inspection enabled?
No
Yes
Is processing complete?
No
Yes
Defects detected beyond allowable limits?
No
Yes
The "accept/reject" flag in set to "reject"
The "accept/reject" flag in set to "accept"
The "accept/reject" flag in set to "reject"
Stop the machine
The "accept/reject" flag in set to "accept"
Display error message
End
n9501pr1.cdr


Process diagram - sheet 2
Container is loaded on conveyor
Container is loaded on worm screw
Container is picked-up by star wheel
Container is detected by proximity sensor
Shift register is updated with "container present" flag
Station TV1: Tip test (see par. 3.2.1)
Station TV2: Tip test (see par. 3.2.1)
Image acquisition and processing (see sheet 1)
Image acquisition and processing (see sheet 1)
To Sheet 3
n9501pr2.cdr


Process diagram - sheet 3
From Sheet 2
Must the container be rejected ?
Yes
No
An air flow keeps the container on the accepted star wheel and it can proceeds to the good channels
An air flow keeps the container on the rejected star wheel and it proceeds to the rejected box
Reject device position is checked
Is reject device operating correctly?
No
Yes
Machine stops
Error message is displayed
Reject box position is checked
No
Has reject box activated limit switch?
Yes
Audible warning is generated
Has number of containers in box exceeded programmed maximum?
Yes
No
No
Is programmed maximum different from 0
Yes
Machine stops
Error message is displayed
To Sheet 4
n9501pr3.cdr


Process diagram - sheet 4
From Sheet 3
The container is inserted on one of accepted channels
Container position is checked
Is the container on the correct channel ?
No
Yes
Machine stops
Error message is displayed
Process complete
n9501pr4.cdr

2.1.2 Mechanics layout

See enclosure 1.

2.2 COMPUTER DESCRIPTION

The computer is housed in a standard 19 inches rack enclosure, containing the computer hardware, the power supply section, the power section and the signal processors for the telecameras. The monitor for the data display and the keyboard are placed externally on a machine table. The rack can be reached by a door which is placed on the left side of the machine.

2.2.1 Hardware architecture

The control system is multiprocessor architecture based, with high speed serial connection among the different processors, to assure real time process control.
It is composed of:

1 - visual display terminal interface (Video Terminal Processor or **VTP**)
2 - a machine handling unit (Machine Processor or **MP**)
3 - various signal processing sub-systems for the inspection stations (Signal Processor, or **SP**)

The power section provides the power supply to control electronics, to the motors and to the various lighting systems.
The telecameras are equipped with a CCD matrix sensor and use standard TV lenses.

Operating

VTP:
- manages the user interface
- programmes the SP sub-systems
- sends test parameters to the SP sub-systems
- stores production data

MP:
- manages movements
- collects the results of SP sub-system tests
- synchronizes movements and tests
- checks the correct operating of all parts and stops the machine in case of malfunction

SPs:
- process the images coming from telecameras and communicate the results of the tests performed to the Machine Processor.

2.2.2 Software architecture

The software of different processing units is stored on solid state components, instead of magnetic media, to avoid the risk of accidental erasure or modification.
A program editor, with "copy" and "modify" functions, and a powerful set of macro instructions makes Signal Processor programming easier; a special test page permits to acquire an image and to execute the program in order to check it.

The control software of the machine is logically subdivided in:

1 - Machine handling software
2 - Programming software

2.2.2.1 Machine handling software

The machine handling software executes the functions typically used by the product manager and the operator, that is:

1- provides the machine normal operation;
2- provides production data, operating warnings and error messages;

The rejects are counted according to a structure consisting of four elements:

1) **Defects**
2) **Stations**
3) **Classes of Defects**
4) **Reject Priority**

Each **Station** can detect up to four **Defects:** for example, the station x can detect at the same time total height and burnings.

Defects can be grouped in **Classes**. A class can include both the defects detected by the same station and the defects detected by different stations: for example, the "Burning" class can include burnings on the tip and on the neck, which are defects detected by separate stations. In this case a container presenting one or both the defects will be counted as reject under the "Burning" class. A class, however, can consist of a single defect as well.
Each inspection (or defect) must belong only to one class. The number of available classes is 16.

Classes are arranged according to a **Reject Priority** order: for example, if the "Burning" class is a priority respect to the "Height" class, the container with both defects will be counted **only** as reject for cracks. (Fig. 2.2)
In the HOME page the number of rejects for each class is displayed. If <ENTER> is pressed when the cursor is positioned on a class, a window pops up which displays the number of rejects for each defect belonging to that class; this display also includes the indication of which stations have detected the defects.
The subdivision into classes of defects can be configured, according to different types and priority of defects.

(For the Classes of Defects and Reject Priority configuration see Appendix B)

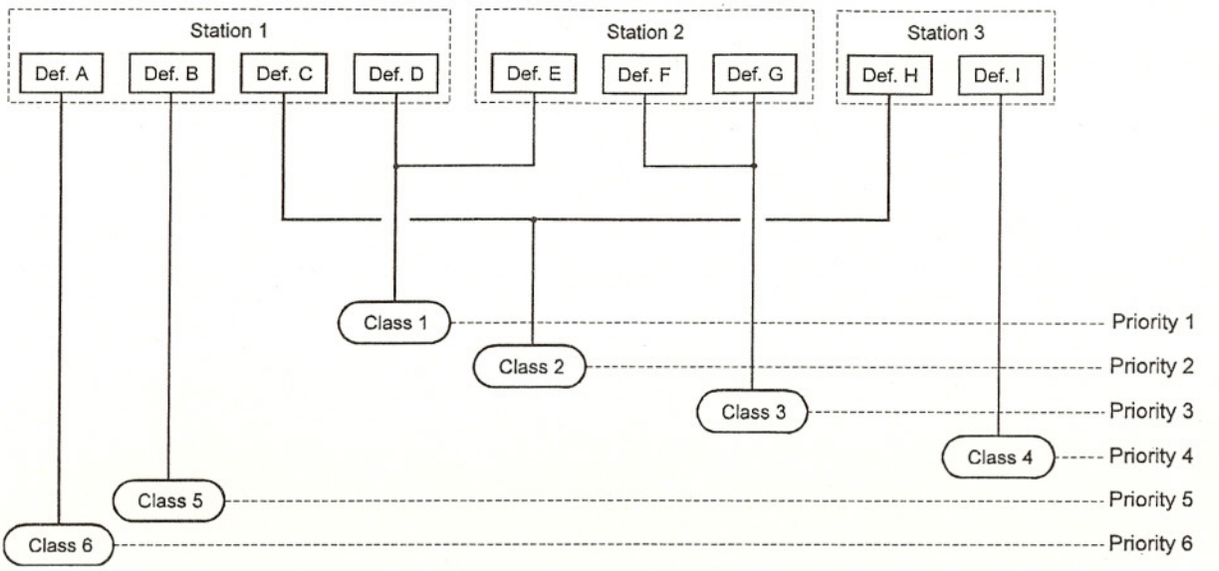


Fig. 2.2

A separate window displays the following data:

Rejects for Machine Stop
Total Rejected
Total Accepted
Total Inspected

3- permits to store and recall the inspection parameters for the products;
4- features some display and print functions useful for monitoring the production and for system operation, such as:

4a) "on line" - that is, in real time - detailed display of the inspection result for each station ("ON LINE" menu): while the machine is operating, the screen displays up to four values of measures performed on the container by the selected station, together with the time taken by the inspection program for processing the image(s). Furthermore, some symbols appear which indicate the presence or absence of the container and whether the container was or was not rejected by the other stations.

4b) comprehensive "on line" graphical display of the inspection result of all stations ("HISTORY" menu): a map of the positions the container fills while it is transported from input to output is displayed; in correspondence to each inspection station a small square appears. If it is green it will indicate that the station accepted the container, if it is red it will indicate that the station rejected the container; in case it appears light blue it will indicate that the station is disabled and did not perform any inspection.

4c) graphical and numerical display of the amount of rejects for each turret spindle ("SPINDLES" menu): the reject percentage of each spindle is shown with a histogram. By selecting a spindle, it is possible to obtain the total containers which it loaded, the total rejected and their percentage. These data is useful to point out possible malfunction of the spindles.

4d) graphical and numerical display of the distribution of the values measured by each station on the last 1000 inspections performed ("GAUSS" menu): once a station has been selected, four quadrants appear. Each quadrant shows the values distribution of one of the quantities analyzed by the program on a max. of 1000 samples (the samples are the last inspections performed by the station; the number of samples can be preset by the user). For each distribution shown, the mean and standard deviation are displayed. Furthermore, a zoom function is available to expand the graph on the x-axis to make it more readable.

4e) possibility of displaying a list of the last 256 alarms occurred during a production lot. Each alarm is displayed complete with date and time. Only the alarms with codes 1-1999 (Operating errors) are listed. These alarms usually involve intervention of a technician to be recovered (see par. 3.4.2). The user can browse the alarm list using <Pg Up> and <Pg Dn> Keys. The contents of the screen can be sent to the printer using <Print Screen> key. When the counters are reset at the beginning of a new lot, the alarm list is cleared.

4f) possibility of entering product and batch data (two 80 character lines available), which is displayed in the "Home" screen (<F7> key).
If the machine is switched off this data remain stored in a non-volatile memory.

5 - features some test functions useful for performing trials on each single test station and on the total efficiency of the machine, such as:

5a) utility for Knapp test execution, with print-out of graphical and numerical report ("KNAPP" menu)

5b) possibility of acquiring an image from any station and immediately execute, with the machine stopped, any processing program for testing purposes ("PROGRAM" menu). It is possible to change parameters and instructions to check their effect without original programs and parameters (which are stored in a non-volatile memory) being changed.

5c) possibility of activating the "Manual" mode ("MANUAL" menu); this is useful, for instance, for format changeover: it permits to disable lamps and motors without the machine diagnosing operating errors.

5d) possibility of acquiring an image from any station and immediately execute different processing for testing purposes ("TEST SP" menu): the gray scale image and the binarized one are shown in separate windows. The user can change the binarization threshold and see the effects on the binarized image. Furthermore it is possible to copy the image in a new window and process it using algorithms as subtraction between two images or convolution.

5e) possibility of activating an "oscilloscope" function ("OSCIL" menu): a window, complete with a reference grid, shows a real time oscilloscope-like display of the light intensity along a row or a column of the image. The user can examine the desired row or column simply by using the four arrow keys. A red line indicates the level of binarization; by changing this level with the <+> <-> keys, the red row moves and gives a help to look for the more appropriate binarization threshold.

5f) possibility of testing the inputs and outputs with the machine stopped ("TEST HW" menu).

6 - includes a complete programming environment, reserved to technical personnel; this permits to write the image processing programs and change the existent ones.
These operations are performed by using an integrated editor; the programs can be saved on non-volatile memory and on removable memory card.

2.2.2.2 Application software

The application software consists of the image processing programs or SP programs.
The programs are written using a language developed by Brevetti C.E.A., which has specific functions for image processing.
Each program is assigned to one or more SP systems and executes on the acquired images the sequence of operations and measures required by the inspection to be performed.
SP Program listings are included in the document [6].

2.3 MACHINE DESCRIPTION

The machine consists of the following main parts:

1) Keyboard and VGA Monitor
2) Machine body
3) Loading table
4) Connecting table with ATM18

The containers loaded on a conveyor belt or coming in-line from the upstream machine, are drawn by a star wheel which at first makes them pass in front of the inspection stations and then addresses them towards the device which divides them into accepted or rejected ones according to the inspection result.

The device, beyond separating goods from rejects, sends the accepted containers to two different channels which are connected in-line with the ATM18 machine. This line is named "first-in first-out" as the first container which enters the line is the first to get out too. The lines are equipped with belts, powered by motors, which are used for the correct operating of the lines themselfs.

The transportation method guarantees a uniform movement of the containers without sudden shifts. This mechanism is built with materials which cannot damage or dirty the containers.

2.4 TECHNICAL NOTES

2.4.1 Performances

Tested containers:	Ampoules
Dimensions of tested containers:	∅ 10.5mm tot.h. 50mm ampoules ∅ 16.5mm tot.h. 67mm ampoules
Machine speed:	300 pcs/min (for 1/2 ml ampoules) 250 pcs/min (for 6 ml ampoules)
Inspection stations:	2 inspection stations
Loading:	from boxes or in line from the upstream machine
Unloading:	accepted: in "first-in first-out" line rejected: standard CEA steel boxes,130x345x50mm (WxDxH)

2.4.2 Services required

Electric supply	220V ±5% 60Hz 1Ph
Power	1.5 KW

2.4.3 Limits

Dimensions: (WxDxH)	2465 x 1250 x 1800
Weight:	1100 Kg
Loading/ unloading height:	900mm ±30mm
Minimum height above floor:	mechanic module: 150mm
Noise: acoustic pressure level (continuous equivalent A-weighted)	75dB(A)
Protection level:	mechanic module: within the CEI standard IP22 cabinet: within the CEI standard IP54

2.4.4 Working environment

Operating temperature:	+5 ÷ +35°C
Relative humidity:	max. 90%, no condensation
Electromagnetic compatibility:	emission within the CEI EN50081-1 standard limits
Pressure:	0.5 ÷ 2 bar

2.4.5 Expandability, interface, options

Software reserve space:	20%
Cabling reserve space:	10% spare terminals
Interface:	serial RS232-C, parallel Centronics
Options:	not applicable
Prearrangements:	not applicable

3. FUNCTIONS

3.1 ACQUISITION SYSTEM

The system of image acquisition and processing is explained into detail in the User Manual. This chapter sums up its operating in order to give an overall view of the techniques used and facilitate the understanding of the tests performed by the machine.

The telecamera has a CCD type matrix sensor (Charge-Coupled Device). The sensor consists of thousands of single elements: each of them supplies a quantity of electric energy proportional to the quantity of luminous power it receives. The circuits of the telecamera measure all voltage values supplied by the single elements of the sensor and build a standard CCIR video signal. This signal is sent by means of a cable to the SP acquisition and processing board. This board samples the signal at a sampling rate of 8MHz, that is, it measures the signal level each 125ns; then it converts the detected value into a number from 0 to 255 (i.e. 0 = black, 127 = gray 50%, 255 = white). A table is created in memory, and it is filled with the numbers coming from the conversion stage. Each one of these numbers represents the quantity of light present in a definite point of the image at the moment of sampling.
This method is called **analog to digital conversion** or **digitizing**.

At this moment there is a 144 x 416 table, whose cells contain all information necessary to understand if the object acquired as an image presents some defects. This map, therefore can be called **"image"**, or, more precisely, **"digitized" image**.
The present system permits to acquire up to **8** images while the container stands in front of the telecamera. The container can be monitored 8 times while it is rotating around its own axis, covering thus the whole lateral surface. In case of flip-off or bottom test, a unique image is sufficient.

3.1.2 PROCESSING SYSTEM

In all the application programs, both using the "difference method" or the "binarized" one, a test is pesrformed in order to check if the quantity of light is enough for the correct execution of the program itself. In the negative the container is rejected termining the program execution. Moreover, if four consecutive rejects occur for lack of light the machine stops and displays the message "Station breakdown".

The first processing the image undergoes is the **"binarization"**: the user defines a threshold between 0 and 255, so that the system assignes the value "0" to all the elements of the digitized image which have a value below this threshold, and assignes the value "1" to the ones which have a value above the threshold. .
Just to make an example, if the object monitored has a middle-grey colour, the image will be a table full of "127" values, corresponding thus to the middle of the range 0-255. If the binarization threshold is set at 128, the resulting binarized image will be a table full of "0" values; if the threshold is set at 126 the table will be full of "1" values.

In this way we obtain one or more binarized images, consisting only of "0" and "1" values. If we test a vial and succeed in lighting it up so that the defects to be detected look **darker** than the vial glass, we will set the binarization threshold at such a value that in the resulting binarized image **the defect becomes a completely black spot on a completely white background** (that is a group of "0" values surrounded by "1" values).

The system can be programmed to look for defects in definite zones of the image, to detect bigger defects than the ones whose dimensions was preset by the user, to make measurements, to detect presence or absence of particulars.

A second technique is the one based on the **"differences"**, that is used for the search of particles inside the fluid.
The container rotates and then abruptly stops so that the particles move inside the fluid while the container stays in front of the telecamera. The SP system is designed to detect only the particles set in movement, so it acquires the first image (that is the one with a value between 0 and 255 for each pixel), then acquires the following ones, comparing at every new acquisition the value of each pixel with the one it had in the first image.
In memory a new table, called **"map of differences"** is built; in this table is inserted a value "1" when in any image a pixel presents a variation respect to the first image equal or above the threshold **(difference threshold)** preset by the user.
In this way only the particles set in movement are marked: parts of the image such as the silk-screen on an ampoule, even though they are very bright or reflecting, they do not produce luminosity variations in time and so they are not detected.

The difference method is used also for the alu-cap inspection and the one concerning the lateral surface of the container. This permits to detect, while the container is rotating, little differences of light due to the presence of cracks or dents.

The Signal Processor can be programmed to process the map of differences in order to look for defects in certain zones of the image or in order to eliminate little disturbances present in the image.

3.2 INSPECTIONS

What follows is a description of all inspection stations installed in the machine.

3.2.1 Station TV1 Station TV2 (Fig. 3.1)

- TIP (SYMMETRY AND BURNINGS)

The test is performed in "instantaneous" way, that is only taking one image while the ampoule is passing with continuous motion in a station which is placed on the transportation star wheel.

Each telecamera, placed above the transportation level of the ampoule, frames the tip by means of a mirror; a lighting unit with halogen lamp and diffuser filter illuminates sideways the tip of the ampoule making the outlines and the possible black points present on the tip appear black on white background. Number 1 points out the test zone of the black points.

By measuring the whole area of the defects and the symmetry of the ampoule tip and comparing these measures with the reference parameters, the system defines if the container must be rejected. The minimum detectable defect, as regards the black point, is a square with a 190μm side, when the contrast between defect and background is equal to 100%.

N.B.: The two telecameras frame the container with a 90° angle the one respect to the other, permitting the check of the whole tip development.

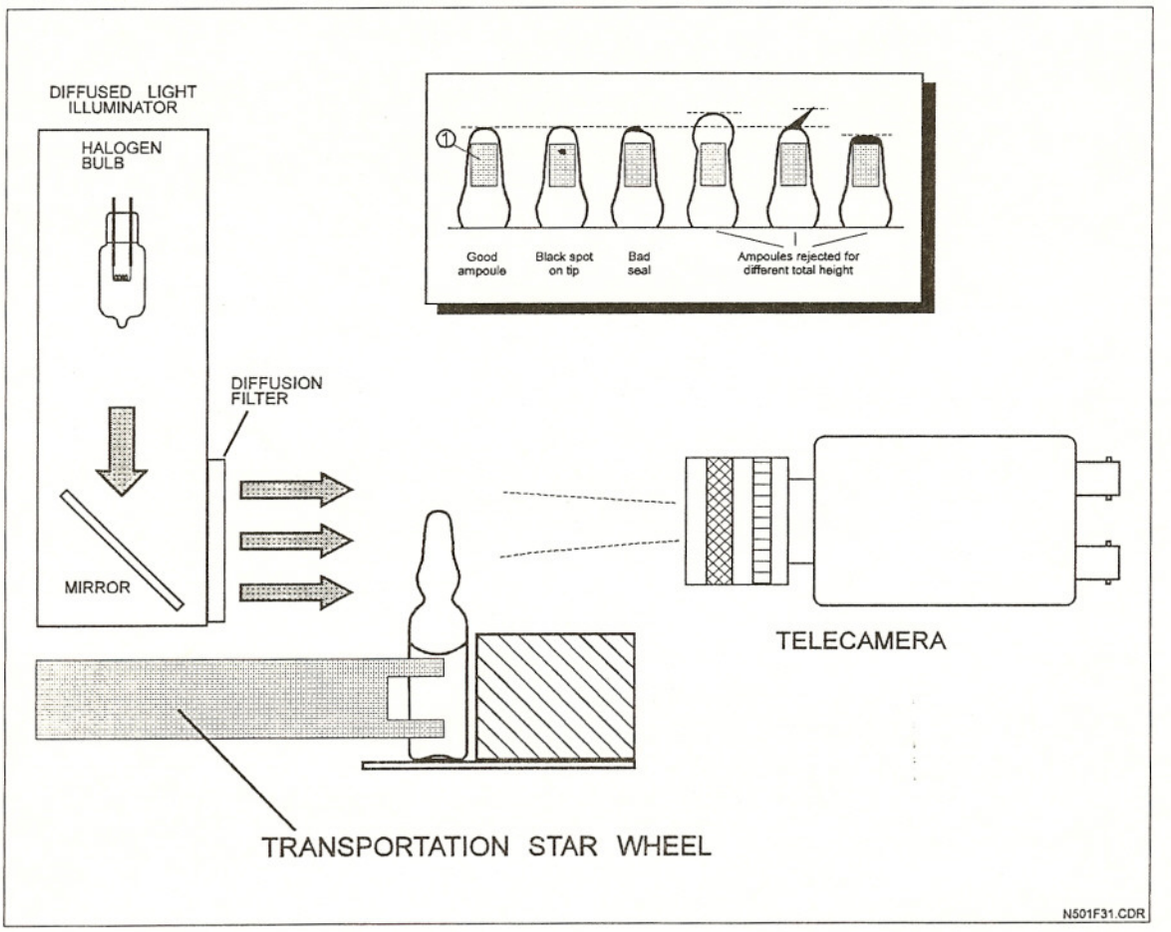


Fig. 3.1 - Station TV1-TV2: Tip test (Symmetry and burnings)

3.3 MECHANICS

3.3.1 Loading

The containers are manually loaded, by means of proper boxes, on a conveyor belt which accumulates them against the transportation star wheel, or automatically draws them by means of a worm screw from a line coming from the upstream machine and directly insert them on the transportation star wheel. The belt, made of a synthetic material, is dragged by a roller connected through a timing belt to a gear motor. The motor speed is controlled by the computer and is preset and stored in the test parameters of the product.
The transportation star wheel rotates with continuous motion and makes the ampoules directly pass in front of the test stations.

3.3.2 Transportation method

The container is transported along the path by a unique star wheel which, beyond making the container pass in front of the inspection stations, moves it to the reject device too (Fig. 3.2).
During the transportation, the containers flow along a steel profile which follows the star wheel circumference.

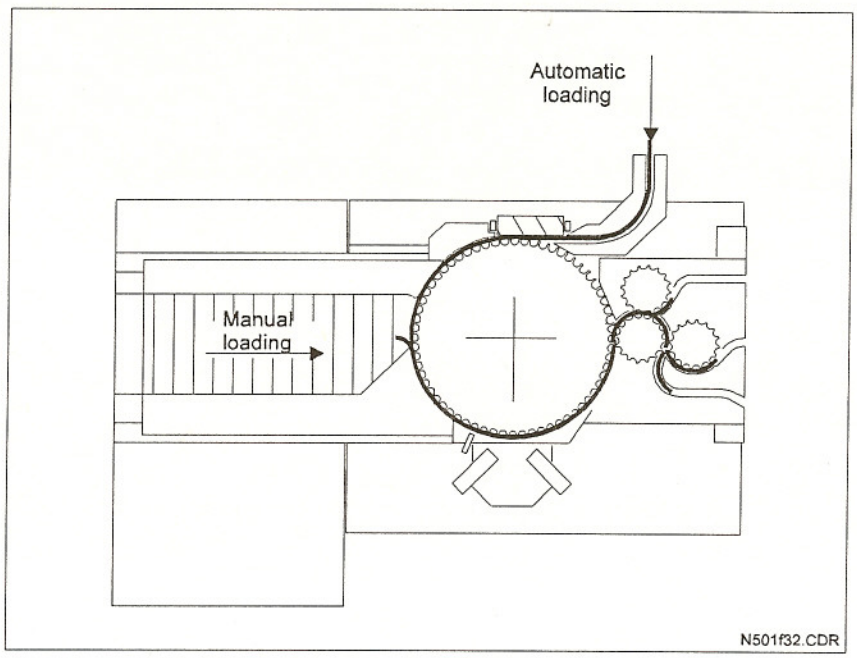


Fig. 3.2 - Containers' path

3.3.3 Output

At the output of the transportation star wheel, the container is drawn by a smaller star wheel. This star wheel moves the container towards the output channels. If the container must be rejected, a proper air actuator moves it to a second star wheel which addresses it towards the output channel of rejects, ending in a box. If the container was accepted, it proceeds and is put on the output channel of accepted. As there are two output channels for accepted containers, these are sent alternatively towards the two channels, by means of a third star wheel. They pass from one star wheel to the other by using the same air principle used for the rejects. Then, by means of belts, are addressed to the downstream machine (ATM18)

3.3.4 Protections

a) All parts in contact with the product are made of stainless steel or of plastic material which does not produce dust and can be removed to permit cleaning.

b) The transportation zone of the containers is separated from the mechanical and electrical parts, so that the product residues can not reach them.

c) The parts in movement are protected by covers equipped with safety switches which stop the machine in case of opening.

d) Access panels to parts that require maintenance can be opened only using a proper tool.

3.4 SAFETY - ERROR AND ALARM MESSAGES

3.4.1 Safety

a) The cover of the loading star wheel is equipped with a device which, in case of opening, stops the machine. When the machine is running the access to moving parts is possible only after actuating a key-switch which cuts out the safety switches.

b) Mushroom-shaped emergency push-buttons are located around the machine in easily accessible positions.
The machine stops in emergency for the following reasons:

1) a mushroom-shaped push-button was pressed
2) a cover was opened

When an emergency stop occurs all parts of the machine stop.
After an emergency stop, the operator must press the emergency-reset push-button to start the machine again.

c) Access panels to parts that require maintenance can be opened only using a proper tool.

d) Parts directly in contact with mains voltage are shielded by insulating panels in order to avoid accidental contacts. The equipment features protections against overloads and earth leakage.

3.4.2 Error and alarm messages

a) Start-up diagnostic test

At power-up, the machine control system performs a series of self-diagnostic tests in order to check the operating condition of the boards and of the printer. The test results are shown on the screen until the user does not make any selection from the keyboard.
The tests performed are in this order:

Memory test
Parameter test
Back-up battery test
Board test
Printer test

The following information is displayed for each test:

Test description	Result	Note

where "result" corresponds to:

"OK" if the test passed
"FAIL" if the test failed

According to the kind of test there can be an additional note: in particular, for the electronic boards equipped with software the note reports the software release, if the test of the program checksum is negative the note reports "FAIL" or "Rel. 000".
The typical self-test screen is shown in figure 3.3.

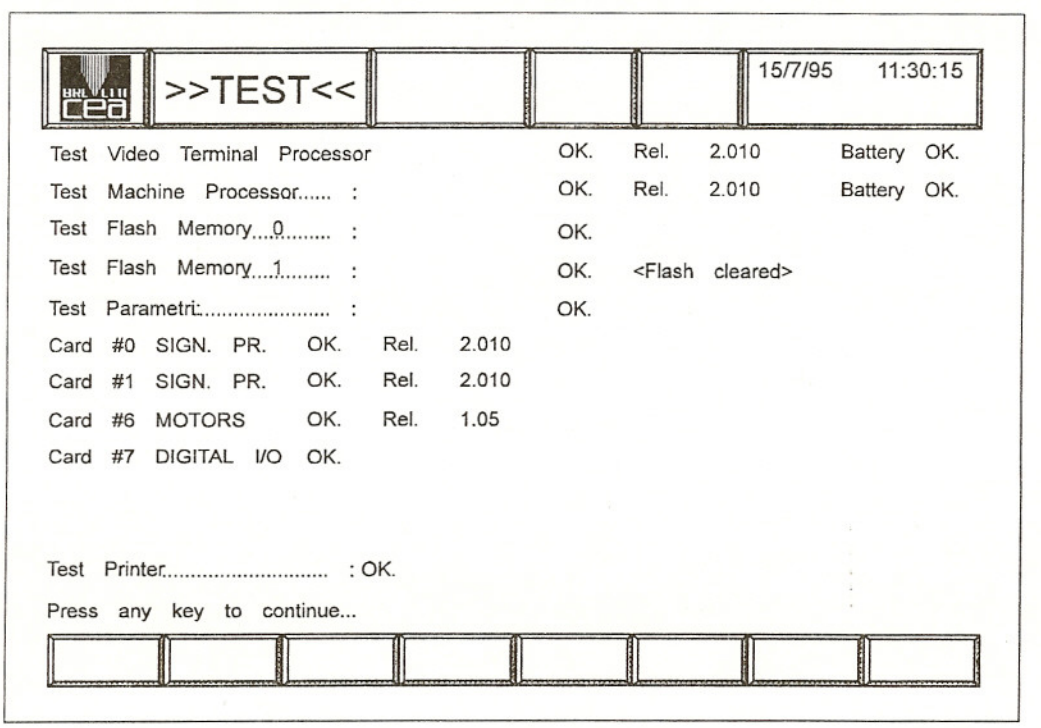

>>TEST<<
15/7/95 11:30:15
Test Video Terminal Processor OK. Rel. 2.010 Battery OK.
Test Machine Processor..... : OK. Rel. 2.010 Battery OK.
Test Flash Memory 0..... : OK.
Test Flash Memory 1..... : OK. <Flash cleared>
Test Parametri:..... : OK.
Card #0 SIGN. PR. OK. Rel. 2.010
Card #1 SIGN. PR. OK. Rel. 2.010
Card #6 MOTORS OK. Rel. 1.05
Card #7 DIGITAL I/O OK.
Test Printer..... : OK.
Press any key to continue...

Fig. 3.3 - Typical Self-Test Screen

b) Operating errors

The error messages are displayed in order to signal the wrong operation of fundamental parts of the machine, that would not allow to correctly test the product.
The error messages listed here below, preceded on the screen by the letter "E", are always associated with an automatic and immediate stop and a 3-second sound signal. Consider them as serious alarms which require the intervention of technical personnel.

MESSAGE	CAUSE	MACHINE CONDITION
Lack of electronics +12VDC supply module (x)	Power section	Stop
Lack of Telecamera +12VDC supply module (x)	Power section	Stop
Lack of Services +24VDC supply module (x)	Power section	Stop
Motor breakdown (y) module (x)	Motor, inverter, belts, encoder, DM522 motor board	Stop
Transmission error MP⇒SP # (y)	Connections, SP board	Stop
Receive error MP⇐SP # (y)	Motor speed too high; Programme too long	Stop
Phase error module (x)	Encoder; DM526 board	Stop
Reject error (y) module (x)	DM526 board; DM532 board; actuator, sensor on actuator	Stop

c) Operational warnings

The operational warnings, preceded on the screen by the letter "W", do not stand for a bad operating of the machine, but they advise the operator when some events occur which can alter the machine operating, or when the operator himself gives an invalid command.
The simple operator's intervention is enough to restore normal condition..

MESSAGE	CAUSE	SOUND SIGNAL	MACHINE CONDITION
Disconnected printer or printer OFF	Printer connections	-----	-----
Function disabled	Operator's error	-----	-----
Inadmissible value	Operator's error	-----	-----
Parameter writing not enabled	Parameter writing key not present	-----	-----
I/O board on MANUAL module (x)	Start with DM526 board on manual	-----	Stop
Motor board on MANUAL module (x)	Start with DM522 board on manual	3 seconds	Stop
Emergency stop module (x)	Emergency push-button; emergency circuit	3 seconds	Stop
Box (y) full module (x)	Excessive number of ampoules; out-of-seat box	Conti-nuous	-----
Stop box (y) full module (x)	Excessive number of ampoules	3 seconds	Stop

4. INTERFACE

All the operations described are performed using the machine's two keyboards:
- **Control keyboard**, located on the front wall of the machine
- **Console keyboard.**

All information is furnished by the **computer screen**, by **the telecamera monitor** and by an optional **printer.**

4.1 ACCESS LEVELS

Operational Functions are accessed via passwords. The system has two access levels:

1. **Operator**
2. **Supervisor**

Two passwords are available for each level. A two character field, which is constantly displayed in the video screen heading, shows the current level code. The level codes which can be displayed are listed below:

- Empty Field:	no level is active, therefore no operational function can be accessed.
- O1:	Operator level is active under password No. 1
- O2:	Operator level is active under password No. 2
- S1:	Supervisor level is active under password No. 1
- S2:	Supervisor level is active under password No. 2

When Operator Level is active, access is restricted to the following operational functions:

1. Start and Stop
2. Counter Reset
3. Active Product Selection

When Supervisor Level is active, access to operational functions is extended and includes:

1. Access to Operator Level Functions
2. Inspection Parameter and Program Modification
3. Password Modification

When the machine is switched on, no level is active, therefore no operational function is enabled. By pressing keys <F7> <F6> <F2> <F1>, the Login command is selected, and the system requests the user to enter a password. After a password is entered, the user accesses the functions reserved to that password, and the video screen heading displays the corresponding level code.
The user can select the Logout command (keys <F7> <F6> <F2> <F2>) to temporarily disable all functions. To access them again, a password must be re-entered.

4.1.1 Operator

4.1.1.1 Machine operations:

A - Starting and stopping

Machine **START** (green) and **STOP** (red) commands are given by illuminated push-buttons present on the control keyboard. Command activation and acceptance are signalled when the push-button lights up.
These commands only permit start-up and stop with the machine in phase.

B - Emergency stop

Immediate machine stop is obtained by pressing one of the self-retaining **EMERGENCY** push-buttons (red mushroom-shaped push-buttons), located around the machine in easily accessible positions.
When the EMERGENCY RESET push-button is illuminated, it signals the condition of emergency stop. At power-up, the machine is set in emergency for safety reasons.

C - Reset after an emergency stop

To restore normal operation you must release the emergency push-button which caused the machine stoppage and press the interested **EMERGENCY-RESET** push-button..
This sequence of operations (Release emergency button-press Reset-press Start) guarantees and protects the machine operator against the possibility of accidental machine start-up after an emergency stop.

4.1.1.2 Operations on the console keyboard:

A - Display of motor speed

GOAL: Display the speed of the machine motors for the active product. This speed is expressed in pieces/ hour for the main motor, in RPM for the rotation motors and in cm/ second for the belt motor.

PROCEDURE: Selection path: <F7> <F1> <F3>

B - Display of production data (Counters)

GOAL: Display of the following data:

- number of tested containers
- number of rejects
- number of rejects divided by test station
- percentages

PROCEDURE: Selection path <F7>

Press the "Print Screen" key to get a print-out of the video page.

C - Start of production batch

GOAL: Set the machine up to test a new production batch. This corresponds to zero the counters and, if necessary, put in the name or the code of a new batch.

PROCEDURE: To zero the counters press the following keys:<F7> <F2> <F1> <F1> and, when required, confirm with <Y>.
Two lines, with 80 alpha-numeric characters each one, are available to enter batch name, batch number or comments, by pressing the keys <F7><F2><F1> and <F5> (INFO)
The "Esc" key deletes a complete line.

D - End of production batch

GOAL: Record the data relative to the inspected batch. It corresponds to print the data referring to the counters and the parameters, with which the inspection was carried out.

PROCEDURE: To print the counters the selection path is:
<F7><Print Screen>
To print the parameters the selection path is:
test parameters - <F7> <F3> <F5> <Print Screen>
motor speed - <F7> <F3> <F5> <Print Screen>

E - Changing the active product

GOAL: Change the type of product being tested. The following parameters are associated with each type of product:

- Name of product
- Sensitivity parameters
- Programs of the different SP sub-systems
- Motor speed
- Parameters for timing the output boxes

Changing the active product automatically changes all the parameters associated with that product.

PROCEDURE: Selection path: <F3><F1>
Position the arrow located in the left part of the display on the row regarding the product to be activated, using the up and down arrow keys <↑> and <↓> .
Press the <F2> key to select the product .
Note that, to confirm acceptance of this command, the name of the chosen product appears on the heading of the video screen.
To create and record a new product refer to the User Manual..

4.1.2 Supervisor

A - Changing a parameter

GOAL: Change one or more parameters associated with the product. To perform this operation it is necessary to own the parameter writing enable key and to insert it on the front panel of the DM503 board. The change is possible only on the parameters of the active product.

PROCEDURE: To make the product active follow the instructions described previously.
To make modifications refer to the User Manual.

B - Print-outs

It is enough to select the desired page and press the <Print Screen> function key.

4.1.3 Maintenance technician

The maintenance technician has a key for safety exclusion, which actuates a switch to disable the safety switches mounted on the machine covers. This permits the machine operating with open covers, in order to perform maintenance or repairing operations. The condition of disabled safety is signalled by the lighting up of a yellow lamp on the panel of the operating keyboard. Each of the two modules has got its own key-switch and its own yellow signal lamp.

5. GLOSSARY

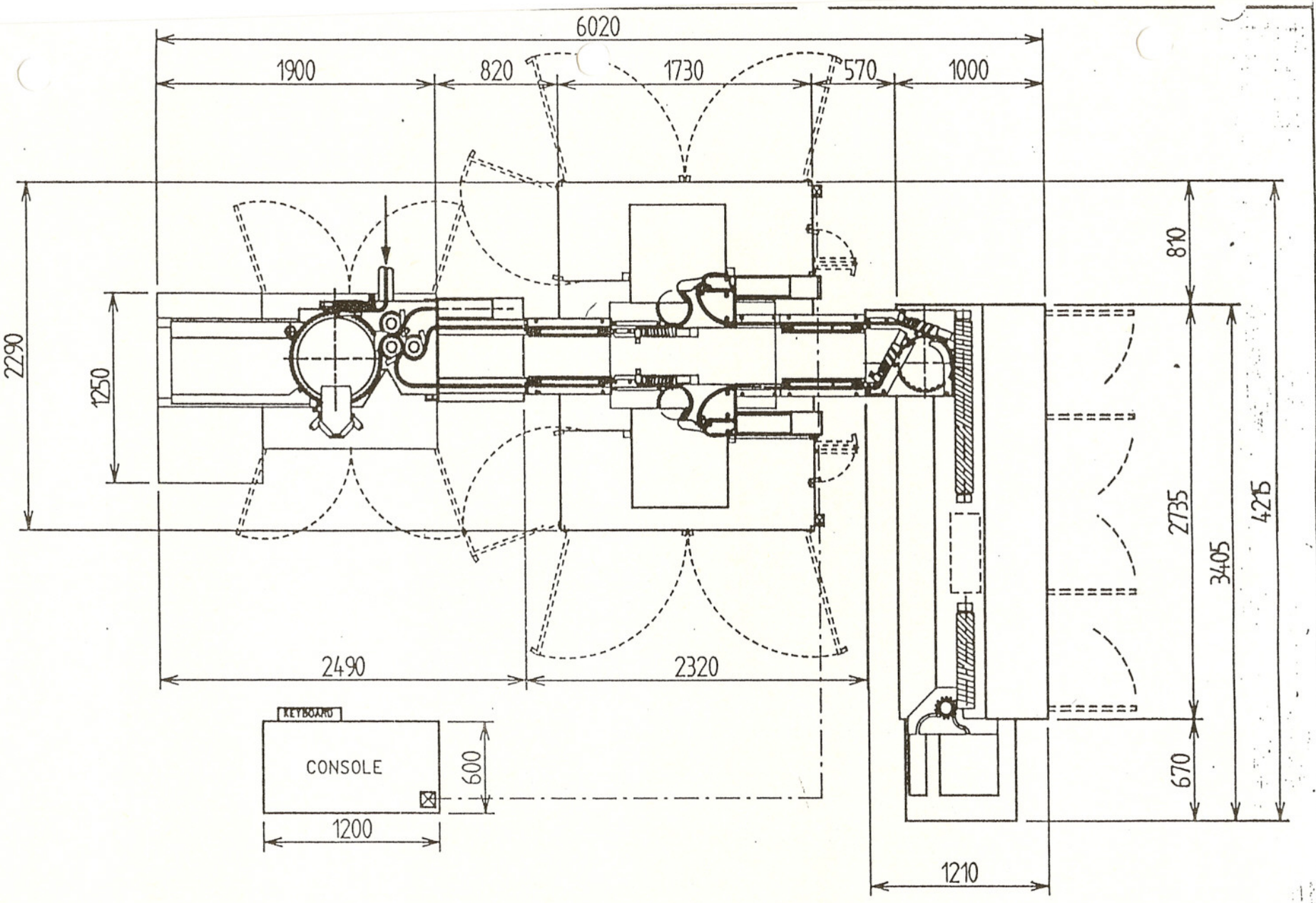
Analog	Quantity or signal which can continuously change. The video signal supplied by the telecamera is analog because it changes in a continuous way analog to the variations of the luminosity of the framed object.
Binarization	Image processing consisting in the conversion of the value of luminosity of each pixel into a binary value, that is 0 or 1, based on a threshold. This permits to obtain an image composed of black and white colours only.
CCD	Charge-coupled device: it is a solid state photosensor where the received luminous energy produces a variation of the electric charge which is picked up and amplified by the telecamera circuits.
CCIR	International Radio Consultative Committee. It stands for a standard format of the video signal.
Digitizing or (analog-to-digital conversion)	Conversion of an analog signal into a series of numbers. At first the analog signal is sampled, in order to have istantaneous values later converted into a number sequence, describing the signal amplitude step by step. The accuracy of the signal translation into numbers depends on the sampling and conversion frequency and on the resolution of the converter circuit. The higher is the frequency, the higher is the resolution and thus the accuracy.
Image	Image stands for the whole numbers resulting from the analog-to-digital conversion: it is a table of numbers, each of them representing the luminosity value in a definite point of the field focused by the telecamera.
MP	Machine processor: it is the processor which controls the machine movements and the correct operating of all parts. After receiving the results of the SP boards tests, it actuates the reject device if the container is considered defected.
Pixel	Contraction of Picture Element: each element composing the image. In the telecamera image a pixel corresponds to what was picked up by one of the photosensors contained in the CCD sensor.
Sampling	Acquisition process of an analog signal: a circuit measures at regular intervals the analog signal applied at its input and at output it gives a sequence of istantaneous values, picked up in the different moments of sampling.
SP	Signal Processor: acquisition and processing circuit, which processes the images coming from the telecameras and communicates the test result to the Machine Processor.
VTP	Video Terminal Processor: it is the computer section which handles the user interface (screen and keyboard): This permits the operator to program the SP processors, to set and store the test parameters and to get the results of the production carried out.

APPENDIX B

Classes of Defects and Reject Priority

		C Tip	L Burn	A	S	S	E	S
	Defects	1	2	3	4	5	6	7
TV 1	Tip seal	X						
	Burnings		X					
TV 2	Tip seal	X						
	Burnings		X					

Each defect is assigned to a class if the corresponding cell is crossed.
Each defect must belong only to one class. Classes are numbered in descending priority order.



ENCLOSURE 1 NN95017

CUSTOMER							
☐ APPROVED ☐ APPROVED AS NOTED		0 — 2 mt	☐ FOR INFORMATION ☐ FOR APPROVAL		TCM + ATM18 DP + LTM		
CUSTOMER SIGNATURE	DATE		DATE	CHECKED	DRAWN	DATE	DWG
			DATE	APPROVED	PF	7.12.95	CONNAUGHT 13
				VICENZA-ITALY			REV. 2